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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,411	12/15/2003	James W. Nicholson	P1682 US (2650/191)	3962

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/736,411

Applicant(s)

NICHOLSON ET AL.

Examiner

Tuan V. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-17 and 19 is/are allowed.
- 6) ☒ Claim(s) 1,5,7-17 and 19-22 is/are rejected.
- 7) ☒ Claim(s) 4 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's arguments filed on January 18, 2007 with respect to claim 20 have been fully considered but they moot in view of new ground of rejection.
2. Based on new search and consideration, Examiner regrets that claims 1, 5, 7-17 and 19 are not allowable over prior art of record (see the rejection set forth below).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1, 5, 7-9 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al (U.S. 6,911,036) further in view Lenz et al. (U.S. 6,620,149).**
6. Referring to claims 1, 5, 7-9, 11-15 and 20-22, Douk et al disclose a system for treating a vascular condition (see Figs. 4 and 5), the system comprising: a hollow Guidewire 144; a core wire 142 inserted through the hollow guidewire, the core wire including an undulating section 160 carried within the hollow guidewire for providing frictional control of the expansion and contraction of an embolic containment device 25 or occluder device based on a direction of axial translation within the hollow guidewire. The tapered undulating section 160 is frictionally contacted an inner surface of the hollow guidewire (see col. 4, line 11 to col. 5, line 8). Douk further discloses an embolic filter device 25 or occluder device 320 (see Fig.13 and col. 8, lines 54-55) coupled between a distal end 27 of the hollow guidewire and a distal end 48 of the core wire. Douk further discloses that different amount of friction can be achieved by selecting the amplitude, or maximal transverse dimension of bends 160 is selected (see col. 5, lines 45-50). Douk discloses the invention substantially as claimed except for the undulation section having a plurality of undulation along an axial portion of the core wire and wherein the tapered undulating section provides lesser friction when the core wire axially translates between a proximal position and a distal position than when the core wire axially translates between the distal position and the proximal position.

7. Still referring to claims **1, 5, 7-9, 11-15 and 20-22**, however, Lenz discloses a core wire having such a feature and intended use of that feature. Lenz discloses a core wire 120 (see Figs. 1 and 6) having a zigzag anchoring structure 122 at the proximal end of the core wire, the proximal portion 122 of core member may be formed into a spiral, or conical helix shape wherein the length, angles circumference and/or spacing of the core member anchor pattern 122 will vary depending upon the length of the proximal shaft section 124 (see col. 5, lines 10-28 and col. 6, line 67 to col. 7, line 53). Lenz further discloses the proximal end 138 of the anchor section 122 is preferably ground which may dig into the plastic inner wall of hub lumen 144, thusly, Lenz discloses the insertion of the core wire 120 into the hypotube is less friction than moving the core wire out of the hypotube. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the plurality of undulation section that decreases linearly with distance from the proximal end of the core wire as disclosed by Lenz into the undulation section as disclosed by Douk to provide the user the ability to deploy the filter and lock the filter from traveling backward during the procedure.
8. Referring to claims **16, 17, and 19**, Douk et al disclose a method for treating a vascular condition (see Figs. 4 and 5) the method comprising: providing a core wire 142 inserted through a hollow guidewire 144, the core wire including a tapered undulating section 160 carried within the hollow guidewire; providing an embolic containment device 25 coupled between a distal end 48 of the hollow

guidewire and a distal end 27 of the core wire; axially translating the core wire in a first direction relative to the hollow guidewire; expanding the embolic containment device based on the axial translation in the first direction; and controlling the axial translation in the first direction based on frictional resistance between the undulating section and an internal surface of the hollow guidewire. The method further comprising: capturing embolic material when the embolic containment device is expanded. The method further comprising: axially translating the core wire 142 in a second direction relative to the hollow guidewire 144; contracting the embolic containment device 25 within the vessel based on the axial translation in the second direction; and controlling the axial translation in the second direction based on frictional resistance between the undulating section and the internal surface of the hollow guidewire (see col. 4, line 11 to col. 5, line 8 and col. 11, line 45 to col. 12, line 2). Douk discloses the method of using his device substantially as claimed by applicant except for the undulating section including a plurality of undulations along an axial portion of the core wire, wherein an amplitude of each consecutive undulation varies with axial distance from a proximal end of the core wire.

9. Still referring to **claim 16**, however, Lenz discloses a core wire having such a feature and intended use of that feature. Lenz discloses a core wire 120 (see Figs. 1 and 6) having a zigzag anchoring structure 122 at the proximal end of the core wire, the proximal portion 122 of core member may be formed into a spiral, or conical helix shape wherein the length, angles circumference and/or spacing of the

core member anchor pattern 122 will vary depending upon the length of the proximal shaft section 124 (see col. 5, lines 10-28 and col. 6, line 67 to col. 7, line 53). Lenz further discloses the proximal end o 138 of the anchor section 122 is preferably ground which may dig into the plastic inner wall of hub lumen 144, thusly, Lens discloses the insertion of the core wire 120 into the hypotube is less friction than moving the core wire out of the hypotube. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the plurality of undulation section that decreases linearly with distance from the proximal end of the core wire as disclosed by Lenz into the undulation section as disclosed by Douk to provide the user the ability to deploy the filter and lock the filter from traveling backward during the procedure.

10. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al in view of Lenz et al. and further in view of Dubrul (Pub. No. U.S. 2004/0236369 A1).**
11. Referring to **claim 10**, the modified device of Douk et al disclose the invention substantially as claimed except for the filter includes a braided wire mesh, and wherein at least a portion of the braided wire mesh is coated with elastomeric material. Dubrul discloses the embolic filter includes a braided wire mesh, and wherein at least a portion of the braided wire mesh is coated with elastomeric material (see paragraph [0057] and [0063]). It would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the filter, as disclosed by Dubrul, to incorporate into the modified device, as

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disclosed by Douk et al because this will reduce the friction between the filament as suggested by Dubrul.

Allowable Subject Matter

12. Claims 4 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
March 27, 2007


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
